From FDA/CDRH to help facilities implement MQSA

Mammography Matters

Spring 1997 Volume 4, Issue 2

From the Editor…

Important October 1997 Dates

Again, we're reminding you of the importance of the personnel requirements that will become effective in October 1997. These requirements were covered in previous issues of Mammography Matters *(Spring 1996, page 11; Summer 1996, page 1; Fall 1996, page 11; and Winter 1997, page 6).*

Under MQSA, all personnel must meet these requirements. In a nutshell, the changes are:

October 1, 1997

By this date most mammography personnel must have earned at least 15 CME/CEU in mammography. The exceptions are those personnel who met their initial qualifications after October 1, 1994.

October 27, 1997

By this date medical physicists who have been using the degree, training, and experience route to meet MQSA qualifications must be:

- *Certified in an FDA-approved specialty by an FDA-approved board, or*
- *State licensed or state approved.*

If you need copies of the previous issues of Mammography Matters *in which these requirements and ways of meeting them were discussed, write to the address in the box on page 8 of this issue. For information on how the continuing education requirement will be calculated, see page 3.*

The Medical Outcomes Audit: What It Means to Your Mammography Practice

Carole Chrvala, Ph.D., Chief of Clinical Research, Division of Mammography Quality and Radiation Programs

A comprehensive medical outcomes audit program can ensure that a facility is providing its patients with the best quality mammography examination and follow-up care. This initial article describes the important elements of a high quality medical outcomes audit system and clarifies the immediate and long-range value of such a system.

Future columns will address the most commonly asked questions about the medical outcomes audit, including practical solutions and/or information about FDA's work in this very important area. Keep in mind that some of the information and advice provided in this column is not presently required by the interim regulations issued under the Mammography Quality Standards of Act of 1992 (MQSA), but is intended to help you develop a better audit system.

The MQSA interim regulations require mammography facilities to collect outcome information about women whose mammograms are positive (i.e., interpreted as suspicious for cancer or highly suggestive

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What's Inside

From the Director . . .

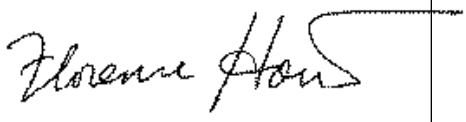
In this issue we are inaugurating a new column written by Dr. Carole Chrvala on mammography medical outcomes audits. This new and developing tool will play a vital role in quality assurance of clinical image interpretation. However, as with any process in its early development stage, it can be very confusing and also frustrating to implement. We are often asked questions such as: What data should I collect? How should I go about obtaining medical outcomes and pathology results? How can I get surgeons and referring physicians to give me medical outcomes feedback? What statistics are interpreting physicians really concerned about?

This new column, about which we are very excited, will give you advice and recommendations (not regulations and requirements) for developing an audit system that works best for your facility and your practice. I'd like to emphasize the words "advice" and "recommendation" because the suggestions this column will provide are just that — advice and recommendations . . . all free from the government!

You are all aware that under the MQSA interim requirements, the inspectors are simply checking to ensure that your facility has an audit system for tracking all positive mammograms. This system should be designed to ensure that all patients who test positive are entered into the system, whether their mammograms are interpreted as suspicious or suggestive of cancer or for which biopsies of any type are recommended. Furthermore, the system must have the potential to obtain pathology information on those patients. Inspectors are also looking to see examples of the medical outcomes you've been able to track (for example, pathology results or reports).

These inspection assessments are very basic. Your audit system should be developed and shaped to suit your practice goals and assist your performance of mammography.

To assist facilities with this process, Dr. Carole Chrvala, formerly the Director of Cancer Control at the Colorado Department of Health and its Colorado Mammography Advocacy Program, recently joined our division at FDA. The Colorado program, which is supported by the Centers for Disease Control and Prevention and the National Cancer Institute, has tracked mammography medical outcomes for over 70 facilities for the past eight years. Dr. Chrvala developed this impressive program, and we are pleased that she will be sharing her expertise in mammography medical outcomes audit with you in Mammography Matters. *Dr. Chrvala will be happy to answer your medical audit questions. Please fax your questions to her c/o* Mammography Matters *at 301-594-3306.*



Florence Houn, M.D., M.P.H.,
Director, Division of Mammography
Quality and Radiation Programs

Interpreting Physicians: Document Your Continuing Experience for MQSA

In order to meet the MQSA continuing experience requirements (see *Mammography Matters:* Spring 1996, page 5; Fall 1996, page 6), it is essential that each interpreting physician document in a simple, organized manner all mammograms that he/she has interpreted. Doing so ensures that a physician's records reflect her/his eligibility to interpret mammograms.

Because physicians may combine totals from different facilities for which they have interpreted mammograms in order to satisfy this requirement, it is very important that each physician keep his/her own records of interpretation.

What do the regulations require?

Under the interim regulations that are currently in effect, interpreting physicians must interpret mammograms for an average of at least 40 patients per month over a 24-month period. This particular aspect of the interim regulations became effective October 1, 1996.

In practical terms this means that, during the inspection, the inspector will count back 24 months from either the date of the inspection or from the end of the previous full calender quarter preceding the inspection date, and determine, for each physician interpreting mammograms at that facility, how many mammograms were read by that individual during that period.

What if this requirement is not met?

If this requirement is not met, the inspector will cite the problem as a Level 2 finding on the inspection report. The physician may continue to read mammograms, but **only under direct supervision** until he/she is requalified. To reestablish qualifications, the physician has six

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The Continuing Education Requirement: How To Figure the Date

After meeting the initial training requirements, all interpreting physicians, radiologic technologists, and medical physicists have a three-year grace period during which they must earn an average of 5 continuing education units (CEUs) per year, or a total of 15 CEUs. For most people, this grace period expires on October 1, 1997.

After that date, MQSA inspectors will let each facility select one of the following two options to determine if their personnel have met the requirement.

Whichever option the facility chooses must be consistently used for *all* interpreting physicians, radiologic technologists, and medical physicists providing services to it.

Option 1

The inspector counts back 36 months from the date of the inspection and includes all applicable continuing education units received by each individual during that 36-month period. For example, if the inspection is conducted on November 10, 1997, the relevant continuing education units for each person would be those earned from November 10, 1994, to November 10, 1997.

Option 2

The inspector counts back 36 months from the end of the full calendar quarter immediately preceding the inspection date and includes all applicable continuing education units received by each individual during that 36-month period. For the inspection date of November 10, 1997, the relevant continuing education units for each person would be those earned from October 1, 1994, through September 30, 1997.

Meeting Training Requirements: What's Acceptable

The October 1, 1997, deadline is nearing for completion of an additional 15 continuing education credits for those interpreting physicians, radiologic technologists, and medical physicists who had met their initial requirements by October 1, 1994 (see *Mammography Matters*, Winter 1997, page 6). As a result, many questions have arisen regarding what is considered acceptable training.

In response to suggestions that the areas of acceptable training be broadened, FDA has reviewed and revised its policy effective January 10, 1997. Consequently, FDA divided the possible training areas into four broad classifications, which are described below.

Definitions

Class 1 training is directly related to production and interpretation of screen-film or xeromammography images. Topics include anatomy and physiology of the breast, positioning, proper technique factors, breast cancer pathology evaluations, imaging of patients with breast implants, quality assurance procedures, and interpretation of screen-film or xeromammographic images.

Class 2 training is related to procedures or modalities under the authority of MQSA but that are presently exempted from regulatory requirements. These procedures or modalities are *expected* to be brought under regulatory requirements in the relatively near future. They include training related to stereotactic biopsy, needle localization, galactography, and digital mammography.

Class 3 training includes all other training related to the detection and treatment of breast cancer, except chemotherapy. Included in this class are:

- Training related to procedures or modalities under the authority of MQSA, presently exempted from MQSA requirements, and *not expected* to be brought under MQSA requirements in the foreseeable future, such as training related to computed tomography imaging of the breast.
- Training related to imaging modalities not included in the MQSA definition of mammography, such as training related to ultrasound and MRI imaging of the breast.
- Training related to breast self-examination, clinical breast examination, and breast cancer treatment methods including surgery and radiation.

Class 4 training includes all other training.

Applying the Classifications

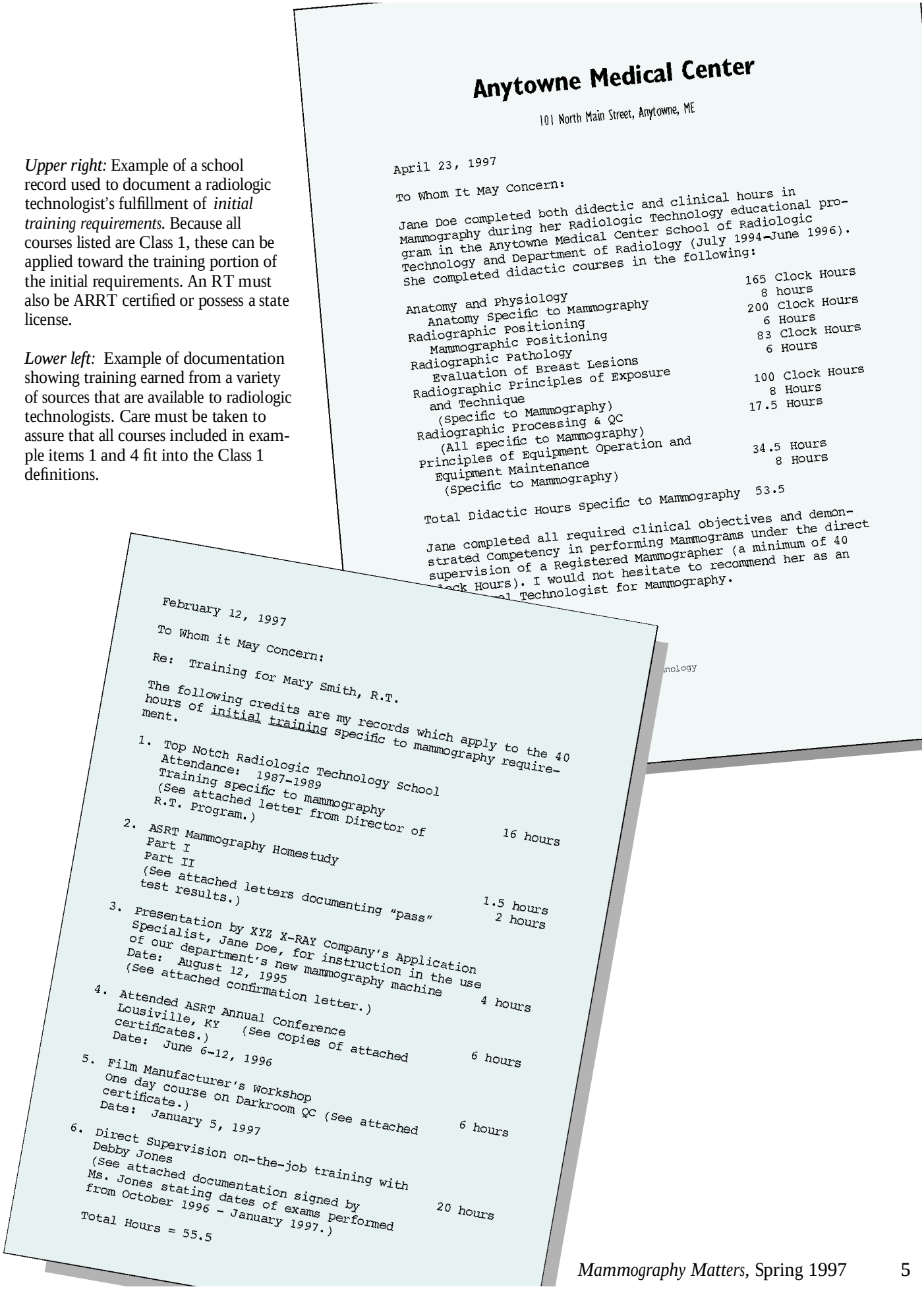
Training earned in each of these class levels may be applied as follows:

- Only Class 1 training can be accepted as meeting the physician requirement of having 40 hours of *initial training* in mammography and the technologist requirement of having *initial training* specific to mammography.
- Class 1, 2, or 3 training can be accepted as meeting the *continuing education requirements* for all three personnel groups. However, at least 50 percent of the training must be in Class 1.
- Training related to procedures or modalities that are under MQSA authority but are currently exempted from the regulations, will be reclassified from Class 2 to Class 1 *if and when* that procedure or modality is brought under MQSA regulations in the future. Examples of this type of training include stereotactic biopsy and digital mammography.

As noted in the Fall 1996 issue of *Mammography Matters*, FDA does not approve training courses. That responsibility lies with professional groups. The agency simply accepts courses as meeting part or all of the training requirements under MQSA.

Upper right: Example of a school record used to document a radiologic technologist's fulfillment of *initial training requirements.* Because all courses listed are Class 1, these can be applied toward the training portion of the initial requirements. An RT must also be ARRT certified or possess a state license.

Lower left: Example of documentation showing training earned from a variety of sources that are available to radiologic technologists. Care must be taken to assure that all courses included in example items 1 and 4 fit into the Class 1 definitions.



Anytowne Medical Center

101 North Main Street, Anytowne, ME

April 23, 1997

To Whom It May Concern:

Jane Doe completed both didectic and clinical hours in Mammography during her Radiologic Technology educational program in the Anytowne Medical Center School of Radiologic Technology and Department of Radiology (July 1994–June 1996). She completed didactic courses in the following:

Anatomy and Physiology	165 Clock Hours
Anatomy Specific to Mammography	8 hours
Radiographic Positioning	200 Clock Hours
Mammographic Positioning	6 Hours
Radiographic Pathology	83 Clock Hours
Evaluation of Breast Lesions	6 Hours
Radiographic Principles of Exposure and Technique	100 Clock Hours
(Specific to Mammography)	8 Hours
Radiographic Processing & QC	17.5 Hours
(All specific to Mammography)	
Principles of Equipment Operation and Equipment Maintenance	34.5 Hours
(Specific to Mammography)	8 Hours
Total Didactic Hours Specific to Mammography	53.5

Jane completed all required clinical objectives and demonstrated Competency in performing Mammograms under the direct supervision of a Registered Mammographer (a minimum of 40 Clock Hours). I would not hesitate to recommend her as an Technologist for Mammography.

nology

February 12, 1997

To Whom it May Concern:

Re: Training for Mary Smith, R.T.

The following credits are my records which apply to the 40 hours of initial training specific to mammography requirement.

1. Top Notch Radiologic Technology School — 16 hours
   Attendance: 1987–1989
   Training specific to mammography
   (See attached letter from Director of R.T. Program.)
2. ASRT Mammography Homestudy — 1.5 hours
   Part I — 2 hours
   Part II
   (See attached letters documenting "pass" test results.)
3. Presentation by XYZ X-RAY Company's Application Specialist, Jane Doe, for instruction in the use of our department's new mammography machine — 4 hours
   Date: August 12, 1995
   (See attached confirmation letter.)
4. Attended ASRT Annual Conference — 6 hours
   Lousiville, KY (See copies of attached certificates.)
   Date: June 6–12, 1996
5. Film Manufacturer's Workshop — 6 hours
   One day course on Darkroom QC (See attached certificate.)
   Date: January 5, 1997
6. Direct Supervision on-the-job training with Debby Jones — 20 hours
   (See attached documentation signed by Ms. Jones stating dates of exams performed from October 1996 - January 1997.)

Total Hours = 55.5

Radiologic Technologist's Training Requirement: Three More Courses Accepted by FDA

FDA has recently accepted three new mammography specific courses that technologists may take to meet their initial training requirement. Although there are other avenues toward acquiring initial training requirements (see *Mammography Matters*, Spring 1996, page 5; and Fall 1996, page 4), these courses are accepted as meeting the requirement in themselves, even though they are less than 40 hours in length.

- "Mammography Instruction for Radiologic Technologists" provided by Oakland Community College of Southfield, Michigan. Carolyn Nacy, 810-552-2610
- "Three Day Mammography Workshop" provided by the Mammographers Radiological Society of Miramar, Florida. Judy Sorge, 954-981-7120
- "Mammography — Quality Performance Assurance," a three day seminar for radiologic technologists provided by Rad Tech Resources, Inc. of Indianapolis, Indiana. Terri Von Tobel, 317-780-5840

These three courses join the two courses previously accepted by FDA as meeting the technologist's initial training requirement:

- "A Three Day Mammography Course for Technologists" provided by Medical Technology Management Institute of Milwaukee, Wisconsin. Denise Sedmak, 1-800-765-6864
- "Initial Training in Mammography" provided by Mammography Imaging Specialists of Portland, Oregon. Joanie Wilmot, 503-659-5022, or Kathleen Durrell, 503-579-4662

FDA evaluates courses for acceptability only if the presenters ask that their program be accepted as meeting the entire training requirement and the course is less than 40 hours in length. Courses that are 40 or more hours in length, or that are less than 40 hours but are presented as meeting only the portion of the 40 hours equal to the length of the course, will be evaluated for acceptability by the inspector.

The Medical Outcomes Audit

Continued from page 1

of malignancy). In response to the request for comments on FDA's proposed final regulations for medical outcomes audits, facilities submitted a wide variety of questions and concerns. We are now reviewing these comments and may make changes, based on these comments, in the final regulations. The final regulations will be published later this year and become effective no sooner than a year after publication.

Currently, mammography facilities are taking many different approaches toward determining what should be included in a medical outcomes audit and how to track the relevant information. As awareness of the value and significance of the information gained from a high quality audit system grows, better systems will be developed. The answers these systems provide will determine what impact your facility has on breast cancer outcomes.

It is a good idea for a facility to complete the following steps as part of its medical outcomes audit program:

- Define regular procedures, methods, or ways in which you can collect information about your patients.
- Decide the content or type of information you want to collect about your patients.
- Decide which patients will be eligible for inclusion in the follow-up process.
- Determine the time frames used to collect your patient information.

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The Medical Outcomes Audit

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- Select the definitions for each piece of information you choose to collect.
- Establish methods or ways to interpret or understand what your outcome data can tell you.
- Decide how to use the data as a source of feedback to improve mammography quality.

As you review the current status of your own medical outcomes audit procedures, consider each of the seven elements above and assess how you are addressing them now. Some of the questions you should ask include:

- Are you finding smaller cancers?
- Are you finding cancers at earlier stages?
- Are your physicians able to offer less invasive treatments to women through the detection of early-stage breast cancer?
- Are you seeing improvements in survival rates from breast cancer?

These questions address some of the most real and meaningful impacts that your medical audit program will have on individual women who are having screening mammograms every day in thousands of mammography facilities nationwide.

A comprehensive medical outcomes audit program can ensure that a facility is providing its patients with the best quality mammography examination and follow-up care.

In subsequent issues of *Mammography Matters*, I will discuss many of the comments and questions FDA received in response to the proposed final regulations, including:

- How to collect data, with practical advice on making the data collection process simple and easily integrated into practice settings.
- What type of follow-up information should actually be collected.
- Suggestions for how technologists and radiologists can work together in (1) analyzing the findings and (2) using the results to either improve mammographic interpretation or inform your medical community about the positive impact you are having on breast cancer detection outcomes.
- Why, at this time, FDA is not requiring follow-up for all women with any type of follow-up recommendation.
- The cost of conducting follow-up for women and practical suggestions for minimizing those costs.

Please contact me through *Mammography Matters* if you have other questions, concerns, and suggestions about medical outcomes audits. (See address and fax number on page 12.)

Carole Chrvala, Ph.D., Chief of Clinical Research for DMQRP, will be writing a regular column for Mammography Matters *regarding medical outcomes audits under MQSA. Dr. Chrvala comes to DMQRP from the Colorado Department of Public Health where she was Director of Cancer Prevention and Control. A graduate of the College of Wooster, she has had faculty appointments in the Department of Preventative Medicine at the University of Colorado Health Sciences Center and recently chaired the National Cancer Institute's (NCI) Breast Cancer Surveillance Consortium. Under grants from NCI, she has worked for the last seven years in mammography medical outcomes research and program implementation.*

Inspector's Advice to a Facility Following a Serious Citation

Under the interim regulations, inspectors cannot order a facility to stop any practice that is, or appears to be, in violation of MQSA. However, when serious problems, such as Level 1 findings, are found at a facility, the inspector will recommend to the facility management that, in the interest of public health, it discontinue using the equipment, personnel, or practice that resulted in the serious conditions.

The inspector may also explain the various sanctions to which the facility could be subject if use of the cited items continues. These include a Directed Plan of Correction, civil money penalties (up to $10,000 per violation), suspension or revocation of the facility's certificate, or an injunction. In addition, continued use of the cited items, while the violative conditions exist, adds to the violations already found.

Continued use of the cited items, while the violative conditions exist, adds to the violations already found.

Some states delegate to their inspectors under state laws, the authority to order a facility to stop a violative practice or to stop performing mammography. When this occurs during the MQSA inspection, the inspector should make it clear to the facility that the action falls under state law and not under MQSA.

While inspectors are very concerned when facilities are in violation of MQSA, in the end it is the responsibility of the facility to comply with MQSA and stop practices that are in violation of the law.

General MQSA Information

Direct your questions about certification and inspection to:

Mammography Quality Assurance Program
Phone 800-838-7715
Fax 410-290-6351

Documents and other MQSA information are available on the Internet at:

http://www.fda.gov/cdrh/dmqrp.html

Submit Requests for MQSA Information to:

MQSA
c/o SciComm, Inc.
PO Box 30224
Bethesda, MD 20824-9998
Fax 301-986-8015

Document Your Continuing Experience for MQSA

Continued from page 3

months to read (1) a sufficient number to bring his/her average up to 40 examinations per month in the previous 24-month period, or (2) mammograms from 240 examinations, whichever is less. Only after requalification may the physician resume reading mammograms independently.

How may these records be maintained?

Physicians may document records by obtaining a letter, table, or printout from each facility, signed by a responsible facility official, stating that he/she has interpreted a given number of mammograms at that facility in a given time period. Alternatively, signed copies of facility logs could be provided.

Since the physician will not know more than a few days in advance when a facility for which he/she interprets will be inspected, the records should be updated frequently.

Good records ensure each physician's ability to accurately document his/her own experience for the MQSA inspector.

Check Your MQSA Certificate Expiration Date!

Nearly three years ago, October 1, 1994, loomed as the starting date for facilities to become FDA-certified. Because MQSA certificates are valid for up to three years, some have expired and many are about to do so.

The starting date of your three-year certificate is the date on which your first mammography unit was accredited. Although your accreditation body will remind you when your units' accreditations are about to expire, it is YOUR responsibility to ensure you complete the reaccreditation process in a timely manner. If you keep your units' accreditations up to date, FDA will be able to mail your new MQSA certificate before your old one expires.

Note that renewal may take as long as the original accreditation. FDA recommends that you apply to renew each unit's accreditation six months prior to its expiration date.

The mention or illustration of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by FDA.

FDA neither endorses nor requires the use of any specific x-ray system component, measuring device, software package, or other commercial product as a condition for accreditation or certification under MQSA.

Any representations, either orally or in sales literature, or in any other form, that purchase of a particular product is required in order to be accredited or certified under MQSA should be reported to FDA immediately so that appropriate action may be taken.

Q & A

Q & A is a regular column in Mammography Matters. *We welcome your questions and will publish answers to any that are of general interest. Send your questions to* Mammography Matters, *FDA/CDRH (HFZ- 240), 1350 Piccard Drive, Rockville, MD 20850, Fax 301-594-3306.*

Q What should our facility do if our MQSA certificate has expired?

A You should stop performing mammography immediately because it is unlawful to do so with an expired certificate. You should determine whether the certificate on display is the only certificate that your facility has, keeping in mind that facility personnel may have forgotten to replace the expired certificate with the current certificate when they received it in the mail. If you have only an expired certificate, you should call your accreditation body for recertification information, or call the FDA MQSA hotline at 1-800-838-7715, and immediately return the expired certificate to FDA at the following address: FDA MQSA, P.O. Box 6057, Columbia, MD 21045-6057.

Q A radiology association reads all of our clinical mammograms. While some of its radiologists may read mammograms for fewer than 40 patients a month for our facility, the radiologists also read for other facilities. Do we need to keep an exact count of mammograms read by each radiologist? As an alternative, is it acceptable for the radiologist to sign a letter saying that he/she read 40 or more mammograms per month in a 24-month period?

A The answer to your first question is "yes." The interpreting physician must obtain a document from each facility at which he/she has worked indicating the number of interpretations performed and the time period in which they were performed by the physician in question. This documentation can be in the form of a simple table or listing based on patient logs, billing records, or other primary records for the MQSA inspector to check. (Also see "Interpreting Physicians: Document Your Continuing Experience for MQSA" on page 3 of this issue of *Mammography Matters*.)

The answer to your second question is "no." FDA does *not* accept attestation for MQSA requirements met after October 1, 1994. An example of attestation is a letter from an interpreting physician stating that he/she read an average of 40 or more mammograms a month for 24 months; such letters are no longer acceptable. However, a letter from the interpreting physician's *supervisor* or from the facility administrator stating the number of mammograms read would be acceptable.

Q If our facility holds on-site training for technologists, what is the guarantee that it will be acceptable for meeting MQSA requirements?

A There is no "guarantee" unless the on-site training is approved by the American Registry of Radiologic Technologists (ARRT) or one of its associated organizations. If facilities organize their own training programs, the inspector will have to do much the same review that is done by the ARRT. The facility must (1) prove to the inspector that the instructors are qualified, (2) provide information on what topics were taught, when the training was held, and for how long the training lasted. This enables the inspector to determine if the courses were appropriate and how much credit should be given. It is not enough for the facility to tell the inspector that it always has its new technologists work with an experienced technologist for a week; the facility must also provide details in writing on what was done during the week.

Q & A *(continued)*

Q Can videotapes be used as part of the training for technologists?

A FDA accepts videotape training under the same rules that the ARRT or its associated groups accept such training. If the provider of the videotape has received ARRT approval, and if the viewer successfully passes the mail-in test that is required for ARRT approval, FDA will accept the viewing of the videotapes for the number of hours specified by the ARRT.

Q Although seminars and refresher courses for medical physicists have increased in availability over the past few years, I still assert that they are hard to come by. Can I count self-study (review of journal articles) as a method of obtaining continuing education credits?

A FDA has decided that it will accept self-study, such as reading books or articles or watching videos, only if it is done through a program approved by a professional body. Training approved by one occupational group can be used by other occupational groups as well.

The ARRT, for example, has a program in which certain articles are identified for credit. The amount of the credit is allotted by the ARRT or an associated group. In order to earn the credits, the individual (an RT, radiologist, or medical physicist) must read the article and pass a mail-in test on the material.

Q Are credits earned for a breast ultrasound course acceptable for meeting MQSA continuing education requirements? Mammography correlation was used in almost all case studies in the training course, but was not specifically mentioned in the course outline or the certificate.

A FDA recently broadened the areas considered acceptable for continuing education credits. At least 50 percent of the average of 5 credits per year must be in Class 1 areas directly related to the quality of mammography. The remaining training can be in almost any area related to the detection or treatment of breast cancer. Therefore, the training in breast ultrasound could be used to meet up to 50 percent of the continuing education requirement. (See "Meeting Training Requirements: What's Acceptable" on Page 4 of this issue.)

Q May an interpreting physician receive credit each time he/she repeats the same course? One of our radiologists has twice taken a home study course with a written test and received a passing score each time. One course was in October 1994, and the other was in 1996. Can the course be counted twice or do credits for different courses need to be obtained within a three-year period to be in compliance with the requirement to earn an average of 5 credits per year?

A Under the present regulations, yes, staff can receive credit for successfully completing the same course more than once. There is no requirement for a minimum time period to lapse before repeating a course.

Q If a physicist receives "state approval" from State A, can he/she perform mammography physics services in State B?

A The regulations follow the law (MQSA itself) in requiring approval by "a" state, not "the" state in which the physicist is working. If a physicist is approved by Pennsylvania, for example, that person meets MQSA requirements to work in any state. However, states are allowed to have more rigorous requirements than MQSA. Therefore, another state may require approval from that state, as well as from Pennsylvania, if the physicist were to work there. If a physicist is cited for lack of such approval, it would be a state citation, not an MQSA citation.

Name and Address Changes:

If your **mailing label code includes** either:
ACR, SAR, SCA, or **SIA,** notify your **accreditation body** of any name and/or address changes.

Otherwise submit your address changes to:
MQSA, c/o SciComm Inc., PO Box 30224, Bethesda, MD 20824-9998.
Fax 301-986-8015.

Please send your comments about or suggestions for *Mammography Matters* to:

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Articles may be reproduced or adapted for other publications. Comments should be addressed to:

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